Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-25 (cancelled)

- 26. (Previously presented) A method of treating prostate cancer comprising administration of a composition comprising:
- (a) mycobacterial DNA (B-DNA) obtained from a disrupted mycobacterium using DNase-free reagents in order to at least partially preserve the DNA; and,
- (b) a pharmaceutically acceptable carrier to an animal or human having prostate cancer in an amount effective to have an antineoplastic effect on prostate cancer in the animal or human having the prostate cancer.
- 27. (Previously Presented) The method of Claim 26, wherein the mycobacterial DNA is obtained from M. smegmatis, M. kansaii, M. fortuitum, M. tuberculosis, M. bovis, M. vaccae, M. avium or M. phlei.
- 28. (Previously Presented) The method of Claim 26, wherein the mycobacterial DNA (B-DNA) is obtained from *M. phlei*.
- 29. (Previously Presented) The method of Claim 26, wherein the pharmaceutically acceptable carrier is mycobacterial cell wall (BCC).
- 30. (Previously Presented) The method of Claim 29, wherein the mycobacterial DNA (B-DNA) is preserved and complexed on the mycobacterial cell wall (BCC).

- 31. (Previously Presented) The method of Claim 26, wherein the pharmaceutically acceptable carrier is *M. phlei* cell wall (MCC).
- 32. (Previously Presented) The method of Claim 31, wherein *M. phlei* DNA is preserved and complexed on the *M. phlei* cell wall (MCC).
- 33. (Previously Presented) The method of Claim 26, wherein the prostate cancer is hormone-sensitive prostate cancer.
- 34. (Previously Presented) The method of Claim 33, wherein the hormone is an androgen.
- 35. (Previously Presented) The method of Claim 34, wherein the androgen is testosterone.
- 36. (Previously Presented) A method of treating prostate cancer comprising administration of a composition comprising:
- (a) mycobacterial DNA (B-DNA) obtained from a disrupted mycobacterium using DNase-free reagents in order to at least partially preserve the DNA; and
- (b) a pharmaceutically acceptable carrier to an animal or human having prostate cancer in an amount effective to have an antineoplastic effect on prostate cancer in the animal or human having the prostate cancer,

wherein the antineoplastic effect is inhibition of proliferation of cancer cells in the prostate, induction of apoptosis in the cancer cells in the prostate, induction of cytokine synthesis in the cancer cells in the prostate, or induction of cytokine synthesis by immune system cells in the prostate.

- 37. (Previously Presented) The method of Claim 36, wherein the cytokine is IL-12 or TNF- α .
- 38. (Previously Presented) The method of Claim 26, wherein the pharmaceutically acceptable carrier is a solid carrier, a liquid carrier, or combination of a solid and liquid carrier.
- 39. (Previously Presented) The method of Claim 26, further comprising administration of anti-androgenic agents, chemotherapeutic agents, steroids, or immunological agents.
- 40. (Currently Amended) A method of treating prostate cancer comprising administration of a composition comprising:
- (a) mycobacterial DNA (B-DNA) obtained from a disrupted mycobacterium using DNase-free reagents in order to at least partially preserve the DNA, wherein the mycobacterial DNA is preserved and complexed on mycobacterial cell wall (BCC); and,
- (b) a pharmaceutically acceptable carrier to an animal or human having prostate cancer in an amount effective to have an antineoplastic effect on prostate cancer in the animal or human having the prostate cancer.
- 41. (Previously Presented) The method of Claim 40, wherein the mycobacterial DNA is obtained from M. smegmatis, M. kansaii, M. fortuitum, M. tuberculosis, M. bovis, M. vaccae, M. avium or M. phlei.
- 42. (Previously Presented) The method of Claim 40, wherein the mycobacterial DNA is obtained from *M. phlei*.
- 43. (Previously Presented) The method of Claim 40, wherein the mycobacterial cell wall is *M. phlei* cell wall (MCC).

- 44. (Previously Presented) The method of Claim 40, wherein the prostate cancer is hormone-sensitive prostate cancer.
- 45. (Previously Presented) The method of Claim 44, wherein the hormone is an androgen.
- 46. (Previously Presented) The method of Claim 45, wherein the androgen is testosterone.
- 47. (Previously Presented) The method of Claim 40, wherein the antineoplastic effect is inhibition of proliferation of cancer cells in the prostate, induction of apoptosis in cancer cells in the prostate, induction of cytokine synthesis by cancer cells in the prostate, or induction of cytokine synthesis by immune system cells in the prostate.
- 48. (Currently Amended) A method of treating prostate cancer comprising administration of a composition comprising:
- (a) mycobacterial DNA (B-DNA) obtained from a disrupted mycobacterium using DNase-free reagents in order to at least partially preserve the DNA, wherein the mycobacterial DNA is preserved and complexed on mycobacterial cell wall (BCC); and,
- (b) a pharmaceutically acceptable carrier to an animal or human having prostate cancer in an amount effective to have an antineoplastic effect on prostate cancer in the animal or human having the prostate cancer,

wherein the antineoplastic effect is induction of cytokine synthesis by cancer cells in the prostate or induction of cytokine synthesis by immune system cells in the prostate, and wherein the cytokine is IL-12 or TNF- α .

- 49. (Previously Presented) The method of Claim 40, wherein the pharmaceutically acceptable carrier is a solid carrier, a liquid carrier, or a combination of a solid and liquid carrier.
- 50. (Previously Presented) The method of Claim 40, further comprising administration of anti-androgenic agents, chemotherapeutic agents, steroids, or immunological agents.

Claims 51-56 (previous numbering mistakes – claims not pending)

Claims 57-65 (cancelled)

- 66. (Currently Amended) A method of treating prostate cancer comprising administration of a composition comprising:
- (a) a predetermined amount of mycobacterial DNA (B-DNA) obtained from a disrupted mycobacterium using DNase-free reagents in order to at least partially preserve the DNA; and,
- (b) a pharmaceutically acceptable carrier to an animal or human having prostate cancer in an amount effective to have an antineoplastic effect on prostate cancer in the animal or human having the prostate cancer, wherein the amount of M-DNA B-DNA administered is from about 0.00001 to about 200mg/kg per dose.
- 67. (Currently Amended) The method of claim 69. Claim 66, wherein the amount of M-DNA B-DNA administered is from about 0.0001 to about 100mg/kg per dose.
- 68. (Currently Amended) The method of claim 69 Claim 66, wherein the amount of M-DNA B-DNA administered is from about 0.001 to about 50mg/kg per dose.
- 69. (New) A method of treating prostate cancer comprising administration of a composition comprising:

Application No. 09/937,643 Response filed December 4, 2003 Reply to Office Action dated June 4, 2003

(a) M. phlei (M-DNA) obtained from a disrupted mycobacterium using DNase-free reagents in order to at least partially preserve the DNA; and,

(b) a pharmaceutically acceptable carrier

to an animal or human having prostate cancer in an amount effective to have an antineoplastic effect on prostate cancer in the animal or human having the prostate cancer.

- 70. (New) The method of Claim 69, wherein the composition is delivered to an animal or human via oral, topical, subcutaneous, intra-prostatical, intra-muscular, intra-peritoneal, intra-venous, intra-arterial, intra-dermal, intra-thecal, intra-lesional, intra-tumoral, intra-bladder, intra-vaginal, intra-ocular, intra-rectal, intra-pulmonary, intra-spinal, transdermal, or subdermal administration; or by placement within cavities of a body, nasal inhalation, pulmonary inhalation, impression into skin or electroporation.
- 71. (New) A method of treating prostate cancer comprising administration of a composition comprising:
- (a) M. phlei-DNA (M-DNA) obtained from a disrupted mycobacterium using DNase-free reagents in order to at least partially preserve the DNA; and,
- (b) a pharmaceutically acceptable carrier

 to an animal or human having prostate cancer in an amount effective to have an
 antineoplastic effect on prostate cancer in the animal or human having the prostate
 cancer,

wherein the antineoplastic effect is inhibition of proliferation of cancer cells in the prostate, induction of apoptosis in the cancer cells in the prostate, induction of cytokine synthesis in the cancer cells in the prostate, or induction of cytokine synthesis by immune system cells in the prostate.

- 72. (New) The method of Claim 71, wherein the composition is delivered to an animal or human via oral, topical, subcutaneous, intra-prostatical, intra-muscular, intra-peritoneal, intra-venous, intra-arterial, intra-dermal, intra-thecal, intra-lesional, intra-tumoral, intra-bladder, intra-vaginal, intra-ocular, intra-rectal, intra-pulmonary, intra-spinal, transdermal, or subdermal administration; or by placement within cavities of a body, nasal inhalation, pulmonary inhalation, impression into skin or electroporation.
- 73. (New) A method of treating prostate cancer comprising administration of a composition comprising:
- (a) M. phlei-DNA (M-DNA) obtained from a disrupted mycobacterium using DNase-free reagents in order to at least partially preserve the DNA, wherein the mycobacterial DNA is preserved and complexed on M. phlei cell wall (MCC); and,
- (b) a pharmaceutically acceptable carrier

 to an animal or human having prostate cancer in an amount effective to have an antineoplastic effect on prostate cancer in the animal or human having the prostate cancer.
- 74. (New) The method of Claim 73, wherein the composition is delivered to an animal or human via oral, topical, subcutaneous, intra-prostatical, intra-muscular, intra-peritoneal, intra-venous, intra-arterial, intra-dermal, intra-thecal, intra-lesional, intra-tumoral, intra-bladder, intra-vaginal, intra-ocular, intra-rectal, intra-pulmonary, intra-spinal, transdermal, or subdermal administration; or by placement within cavities of a body, nasal inhalation, pulmonary inhalation, impression into skin or electroporation.
- 75. (New) A method of treating prostate cancer comprising administration of a composition comprising:
- (a) M. phlei-DNA (M-DNA) obtained from a disrupted mycobacterium using DNase-free reagents in order to at least partially preserve the DNA, wherein the mycobacterial DNA is preserved and complexed on M. phlei cell wall (MCC); and,

Application No. 09/937,643 Response filed December 4, 2003 Reply to Office Action dated June 4, 2003

(b) a pharmaceutically acceptable carrier

to an animal or human having prostate cancer in an amount effective to have an antineoplastic effect on prostate cancer in the animal or human having the prostate cancer,

wherein the antineoplastic effect is induction of cytokine synthesis by cancer cells in the prostate or induction of cytokine synthesis by immune system cells in the prostate, and wherein the cytokine is IL-12 or $TNF-\alpha$.

76. (New) The method of Claim 75, wherein the composition is delivered to an animal or human via oral, topical, subcutaneous, intra-prostatical, intra-muscular, intra-peritoneal, intra-venous, intra-arterial, intra-dermal, intra-thecal, intra-lesional, intra-tumoral, intra-bladder, intra-vaginal, intra-ocular, intra-rectal, intra-pulmonary, intra-spinal, transdermal, or subdermal administration; or by placement within cavities of a body, nasal inhalation, pulmonary inhalation, impression into skin or electroporation.

- 77. (New) A method of treating prostate cancer comprising administration of a composition comprising:
- (a) a predetermined amount of *M. phlei*-DNA (M-DNA) obtained from a disrupted mycobacterium using DNase-free reagents in order to at least partially preserve the DNA; and
 - (b) a pharmaceutically acceptable carrier

to an animal or human having prostate cancer in an amount effective to have an antineoplastic effect on prostate cancer in the animal or human having the prostate cancer, wherein the amount of M-DNA administered is from about 0.00001 to about 200mg/kg per dose.

Application No. 09/937,643 Response filed December 4, 2003 Reply to Office Action dated June 4, 2003

78. (New) The method of Claim 77, wherein the composition is delivered to an animal or human via oral, topical, subcutaneous, intra-prostatical, intra-muscular, intra-peritoneal, intra-venous, intra-arterial, intra-dermal, intra-thecal, intra-lesional, intra-tumoral, intra-bladder, intra-vaginal, intra-ocular, intra-rectal, intra-pulmonary, intra-spinal, transdermal, or subdermal administration; or by placement within cavities of a body, nasal inhalation, pulmonary inhalation, impression into skin or electroporation.